

REMARKS

Claims 16-26 are pending.

Claims 16 and 26 are amended. Support for the amendment to claim 16 is found in Figs. 1-6 and page 4, lines 21-22.

Claims 16-26 are rejected.

CLAIM REJECTION – 35 U.S.C. § 112

Claim 26 is rejected under 35 U.S. C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 26 has been amended to more clearly point out the claimed invention. Accordingly, Applicants respectfully submit that the rejection of Claim 26 under 35 U.S.C. 112, second paragraph should be withdrawn.

CLAIM REJECTION – 35 U.S.C. § 103

Claims 16-18 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley (U.S. Patent No.: 5,415,629).

Applicant's invention is directed to a device for transdermal administration of nicotine including two parts. The first part is a patch and the second part is a variety of means that are activatable by the user of the device and the two parts are contained in one unit.

The Office Action alleges that Henley teaches a device for transdermal administration that is a programmable iontophoretic and ionosonic drug delivery apparatus. The iontophoretic device and ionosonic device of Henley only corresponds to an embodiment of the second part of Applicant's claimed device. While Henley

teaches combining the ionosonic programmable or iontophoretic drug device with a passive pain relieving patch for the short acting narcotic Fentanyl®, there is no teaching or suggestion in Henley of combining a passive and programmable device in one unit for the administration of nicotine as claimed and as described in the examples of the present application.

In fact, Henley at column 4, lines 52 – 59, teaches that its device should be used to provide the total daily dose of nicotine without using a passive patch. This is described as delivering the total daily dose “in an intelligent, responsive dynamic manner to improve efficacy while decreasing the total daily dose when compared to current passive delivery systems such as the nicotine patch.” Therefore Henley teaches away from combining a programmable device with a passive patch when delivering nicotine.

The claimed invention is instead a unitary two-part device that includes a patch, for administration of nicotine. The unitary device of the claimed invention provides ease of use and wearability. This improvement is not taught or suggested by Henley.

Accordingly, Applicants respectfully submit that the rejection of claims 16-18 and 25-26 under 35 U.S.C. 103 (a) as being unpatentable over Henley is improper and should be withdrawn.

Claims 19–24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley (U.S. Patent No.: 5,415,629), as applied to claims 16-18 and 25 above and in further view of Hansson (U.S. 2004/0191322).

As discussed above, Henley does not teach or suggest Applicant's claimed unitary device. Hansson only teaches that certain forms of nicotine may be administered transdermally. This teaching does not relate to either the function or the unitary character of the claimed device. Therefore the teaching of Hansson does not

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make up the deficiency in Henley and their combination fails to teach or suggest the claimed invention.

Applicants respectfully submit that the rejection of claims 19-24 under U.S.C. 35 U.S.C. 103(a) as being unpatentable over Henley in view of Hanson is improper and should be withdrawn.

Respectfully submitted,

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